4.1 Management Responsibility

No.	Question	Y	N	Comments
	4.1.1 Quality Policy			
1	Has the supplier's management with executive responsibility defined and documented it's policy for quality?			
2	Does the documented quality policy include the supplier's objectives for quality and commitment to quality?			
3	Is the quality policy relevant to the supplier's organizational goals and expectations and needs of it's customers?			
4	Is the quality policy understood, implemented and maintained at all levels of the organization?			
	4.1.2 Organization			
	4.1.2.1 Responsibility and Authority			
5	Have the responsibilities, authority of personnel who manage, perform and verify work affecting quality been defined and documented? (E.g.: job descriptions, procedures, functional descriptions, etc.)			
6	Has the interrelationship of personnel noted above been defined as documented? (E.g.: organizational charts, etc.)			
	4.1.2.2 Resources			
7	Have resource requirements been identified and provided?			
8	Do the above resource requirements include the assignment of trained personnel for management, performance of work and verification activities including internal quality audits?			
	4.1.2.3 Management Representative			
9	Has the supplier's management with executive responsibility appointed a member of its own management as the ***Management Representative***?			
10	Does the management representative have the defined authority to: a) Ensure the quality system is established, implemented and maintained in accordance with ISO 9001 or ISO 9002?			
	b) Report on the performance of the quality system to the supplier's management for review and as a basis for improvement of the quality system?			

No.	Question	Y	N	Comments
	4.1.3 Management Review			
11	Does the supplier's management with executive responsibility review the quality system at defined intervals?			
12	Is the nature and frequency of the quality system reviews sufficient to ensure it's continuing suitability and effectiveness in satisfying the requirements of the relevant ISO standard and the supplier's quality policy and objectives?			
13	Are records of quality system reviews maintained as quality records?			

4.2 Quality System

No.	Question	Y	N	Comments
	4.2.1 General			
1	Has the supplier established and documented the quality system?			
2	Is the quality system maintained?			
3	Has a quality manual been prepared which addresses the requirements of ISO 9001 or ISO 9002?			
4	Does the quality manual include or make references to the documented procedures that form the quality system?			
5	Does the quality manual outline the structure of the documentation used in the quality system?			
	4.2.2 Quality System Procedures			
6	Have written procedures been established which address:			
	a) Management responsibility			
	b) Quality system			
	c) Contract review			
	d) Design control			
	e) Document and data control			
	f) Purchasing			
	g) Control of customer supplied product			
	h) Product identification and traceability			
	i) Process control			
	j) Inspection and testing			
	k) Control of inspection, measuring and test equipment			
	l) Inspection and test status			
	m) Control of nonconforming product			
	n) Corrective and preventive action			
	o) Handling, storage, packaging, preservation and delivery			
	p) Control of quality records			
	q) Internal quality audits			
	r) Training			
	s) Servicing			
	t) Statistical techniques			

No.	Question	Y	N	Comments
	4.2.3 Quality Planning			
7	Has the supplier defined and documented how the requirements will be met?			
8	Is quality planning consistent with all other requirements of the supplier's quality system?			
9	Is quality planning documented in a format suitable to the supplier's method of operation?			
10	Has consideration been given to the following activities (as appropriate):			
	a) The preparation of quality plans?			
	b) The identification and acquisition of any controls, processes, equipment, fixtures, resources and skills that may be needed?			
	c) Ensuring the compatibility of the design, the production process, installation, servicing, inspection and test procedures and the applicable documentation?			
	d) The updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation?			
	e) The identification of any measurement requirement involving capability that exceeds the known state of the art, in sufficient time for the capability to be developed?			
	f) The identification of suitable verification at appropriate stages in the realization of product?			
	g) The clarification of standards of acceptability for all features and requirements, including those which contain a subjective element?			
	h) The identification and preparation of quality records?			

4.3 Contract Review

No.	Question	Y	N	Comments
1	**4.3.1 General** Has a document procedure been established for contract review and for coordination of contract review activities?			
2	**4.3.2 Review** Before submission of a tender or acceptance of a contract or order are the tender, contract or order reviewed to ensure that: a) The requirements are adequately defined and documented?			
	b) If telephone (verbal) orders are taken, are these recorded in order that the written order can be compared to previous agreements?			
	c) Any differences between the contract or order requirements and those in the tender are resolved?			
	d) The supplier has the capability to meet the contract or order requirements?			
3	**4.3.3 Amendment to a Contract** Does the supplier have a procedure identifying how a contract is amended and correctly transferring the information to functions concerned within the organization?			
4	**4.3.4 Records** Are records of contract review maintained as quality records?			

4.4 Design Control

No.	Question	Y	N	Comments
	4.4.1 General			
1	Have documented procedures been established to control and verify the design of the product?			
	4.4.2 Design and Development Planning			
2	Has the supplier prepared plans for each design and development activity?			
3	Do the plans describe or reference these activities?			
4	Are personnel assigned to design and design verification activities qualified?			
5	Are they equipped with adequate resources?			
6	Are design plans updated as the design evolves?			
	4.4.3 Organizational and Technical Interfaces			
7	Have organizational and technical interfaces between different groups which input into the design process been defined?			
8	Is the necessary information documented, transmitted and regularly reviewed?			
	4.4.4 Design Input			
9	Are design input requirements identified, documented and reviewed for adequacy?			
10	Are statutory and regulatory requirements identified during the design input phase?			
11	Are incomplete, ambiguous or conflicting requirements resolved with those responsible for imposing the requirements?			
12	Does design input take into consideration the results of any contract review activities?			
	4.4.5 Design Output			
13	Is design output documented an expressed in terms that can be verified and validated against design requirements?			
14	Does design output: a) Meet the design input requirements?			
	b) Contain or make references to acceptance criteria?			
	c) Identify those characteristics in the design that are crucial to the safe and proper functioning of the product?			

No.	Question	Y	N	Comments
15	Are design output documents reviewed prior to release?			
	4.4.6 Design Review			
16	Are formal document reviews of the design planned and conducted at appropriate stages of the design process?			
17	Do design reviews include representatives of all functions concerned with the design stage being reviewed?			
18	Are records of design reviews maintained as quality records?			
	4.4.7 Design Verification			
19	Is design verification performed to ensure design stage output meets the design stage input requirements?			
20	Are design verification measures recorded ? (quality records)			
	4.4.8 Design Validation			
21	Is design validation performed to ensure that the product conforms to defined user needs and/or requirements?			
	4.4.9 Design Changes			
22	Are design changes and modifications identified, documented, reviewed and approved by authorized personnel prior to their implementation?			

4.5 Document and Data Control

No.	Question	Y	N	Comments
	4.5.1 General			
1	Is there a documented procedure to allow for control of all documents and data that relate to the quality system?			
2	Does the document control procedure include documents of external origin such as standards and customer drawings?			
	4.5.2 Document and Data Approval and Issue			
3	Are documents and data reviewed and approved by authorized personnel prior to issue?			
4	Is there a master list or equivalent document control procedure that identifies the current revision status of documents and is it readily available?			
5	Do controls ensure that: a) Pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed?			
	b) Invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use?			
	c) Any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified?			
	4.5.3 Document and Data Changes			
6	Are changes to documents and data reviewed and approved by the same function/organization that performed the original review and approval?			
7	If specified otherwise, do the designated functions/organizations have access to pertinent background information upon which to base their review and approval?			
8	Is the nature of the change identified in the document or appropriate attachment where practicable?			

4.6 Purchasing

No.	Question	Y	N	Comments
	4.6.1 General			
1	Have documented procedures been established to ensure purchased product conforms to requirements?			
	4.6.2 Evaluation of Subcontractors			
2	Are subcontractors evaluated and selected on the basis of their ability to meet subcontracted requirements?			
3	Are quality system and any specific quality assurance requirements included in the evaluation and selection process?			
4	Is the type and extent of control to be exercised over subcontractors defined?			
5	Does the supplier have records of acceptable subcontractors?			
	4.6.3 Purchasing Data			
6	Do purchasing documents contain data clearly describing the product or service being ordered?			
	Including where applicable			
	a) The type, class, grade or other precise identification?			
	b) The title or other positive identification, and applicable issue (revision) of specifications, drawings, process requirements, inspection instructions and other relevant technical data?			
	c) The requirements for approval or qualification of product procedures, process equipment and personnel?			
	d) The title, number and issue of the quality system standard to be applied?			
7	Are purchasing documents reviewed and approved by the supplier for adequacy prior to release?			
	4.6.4 Verification of Purchased Product			
	4.6.4.1 Supplier Verification at Subcontractor's Premises			
8	Are verification arrangements and the method of product release specified in the purchasing documents where the supplier proposes to verify purchased product at the subcontractor's premises?			
	4.6.4.2 Customer Verification of Subcontracted Product			
9	Where specified in the contract, do the supplier's purchasing documents afford the customer the			

No.	Question	Y	N	Comments
	right-of-access for verification?			

4.7 Control of Customer Supplied Product

No.	Question	Y	N	Comments
1	Have documented procedures been established for control of verification, storage and maintenance of customer supplied product?			
2	Do the procedures for customer supplied product include provisions for recording and reporting to the customer product that is lost, damaged or otherwise unsuitable for use?			

4.8 Product Identification and Traceability

No.	Question	Y	N	Comments
1	Are documented procedures established for identifying items and products by suitable means from receipt and during all stages of production, delivery and installation?			
2	Are documented procedures available for traceability where appropriate?			
3	When traceability is a specified requirement is the product or batches thereof uniquely identified?			
4	Is this identification recorded?			

4.9 Process Control

No.	Question	Y	N	Comments
1	Has the supplier identified and planned the production, installation and servicing processes which directly affect quality?			
2	Are these processes carried out under controlled conditions? Do controlled conditions include: a) Documented procedures defining the manner of production, installation or servicing?			
	b) Use of suitable equipment and working environment?			
	c) Compliance with reference standards/codes, quality plans and/or documented procedures?			
	d) Monitoring and control of suitable processes parameters and product characteristics?			
	e) The approval of processes and equipment, as appropriate?			
	f) Stipulating the criteria for workmanship in the clearest practical manner? (E.g.: written standards, representative samples or illustrations)			
	g) Suitable maintenance of equipment to ensure continuing process capability?			
3	Are processes which cannot be fully verified by subsequent inspection or testing (***Special Processes***) carried out by qualified operators and/or is continuous monitoring applied to process parameters?			
4	Are requirements for qualification of process operations, including associated equipment and personnel specified?			
5	Are records maintained for qualified processes, equipment and personnel?			

4.10 Inspection and Testing

No.	Question	Y	N	Comments
	4.10.1General			
1	Has the supplier established documented procedures for inspection and testing activities in order to verify that the specified requirements are met?			
2	Does the quality plan or documented procedure state the required inspection or tests and the records to be established?			
	4.10.2Receiving Inspection and Testing			
3	Does the supplier ensure that incoming product is not used or processed until it has been inspected and determined to be conforming? (Except in circumstances as noted below in question 6)			
4	Is verification of conformance to the specified requirement in accordance with the quality plan and/or documented procedures?			
5	Is consideration given to the amount of control exercised at the subcontractor's premises and recorded evidence of conformance when determining the amount and nature of receiving inspection?			
6	If incoming product is released for urgent production, is it positively identified and recorded in order to permit recall and replacement in the event it is later determined to be nonconforming?			
	4.10.3In-process Inspection and Testing			
7	Is the product inspected and tested as required by the quality plan or documented procedures?			
8	Is product held until the required inspections and tests have been completed or necessary reports have been received and verified? (Except as noted in question 6 above)			
	4.10.4Final Inspection and Testing			
9	Are all final inspections and test carried out in accordance with the quality plan and/or documented procedures?			
10	Do quality plans or documented procedures require that all specified inspections and tests (including receiving and in-process inspections and tests) have been carried out and the results meet specified requirements?			
11	Do the suppliers procedures ensure that no product is dispatched until all activities specified in the quality plan or documented procedure have been satisfactorily completed and the associated data and documentation is available and authorized?			

No.	Question	Y	N	Comments
	4.10.5Inspection and Test Records			
12	Are records established and maintained which provide evidence that the product has been inspected and/or tested?			
13	Do the records clearly show whether the product has passed or failed the inspection and/or tests according to defined acceptance criteria?			
14	Do record identify the inspection authority responsible for release of the product			

4.11 Control of Inspection, Measuring and Testing Equipment

No.	Question	Y	N	Comments
	4.11.1General			
1	Are documented procedures established to control, calibrate and maintain inspection, measuring and test equipment (including test software) that is used to demonstrate the conformance of product to the specified requirements?			
2	Is inspection, measuring and test equipment used in a manner which ensures that the measurement uncertainty is known and is consistent with the required capability?			
3	Is test software or comparative references such as test hardware checked to prove that they are capable of verifying the acceptability of product prior to release for production, installation or servicing?			
4	Is test software of comparative references such as test hardware rechecked at prescribed intervals?			
5	Has the supplier established the extent of such checks and are records of these checks maintained?			
6	Is technical data pertaining to inspection, measuring and test equipment made available to the customer or customer's representative when this is a specified requirement?			
	4.11.2Control Procedure			
7	Has the supplier determined the measurements to be made and the accuracy required?			
8	Is the appropriate inspection, measuring and test equipment selected that is capable of the necessary accuracy and precision?			
9	Is all inspection, measuring and test equipment that can affect product quality identified, calibrated and adjusted at prescribed intervals, or prior to use, against verified equipment having a known valid relationship to internationally or nationally recognized standards?			
10	Where no such standards exist is the basis for calibration documented?			

No.	Question	Y	N	Comments
11	Has the process to be employed for calibration of inspection, measuring and test equipment been defined? Including details of: a) Equipment type? b) Unique identification? c) Location? d) Frequency of checks? e) Check method? f) Acceptance criteria? g) Action to be taken when results are unsatisfactory?			
12	Is inspection, measuring and test equipment identified with a suitable indicator or approved identification record to show the calibration status?			
13	Are calibration records maintained for inspection, measuring and test equipment?			
14	Is the validity of previous inspections and test results assessed and documented when inspection, measuring and test equipment is found to be out of calibration?			
15	Does the supplier ensure that the environmental conditions are suitable for the calibration, inspections, measurements and tests to be carried out?			
16	Does the supplier ensure that the handling , preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use is maintained?			
17	Are inspection, measuring and test facilities, including both test hardware and test software, safeguarded from adjustments which would invalidate the calibration setting?			

4.12 Inspection and Test Status

No.	Question	Y	N	Comments
1	Is the inspection and test status of product identified by suitable means to indicate the conformance or nonconformance of product with regard to the inspections and tests performed?			
2	Is the identification of inspection and test status maintained, as defined in the quality plan and/or documented procedures, throughout production, installation and servicing?			
3	Does the quality plan and/or documented procedures ensure that only product that has passed the required inspections and tests is dispatched, used or installed?			

4.13 Control of Nonconforming Product

No.	Question	Y	N	Comments
	4.13.1General			
1	Has the supplier established documented procedures to ensure that product that does not conform to specific requirements is prevented from unintended use or installation?			
2	Does this control provide for:			
	a) Identification?			
	b) Documentation?			
	c) Evaluation?			
	d) Segregation (when practical)?			
	e) Dispositioning?			
3	Does this control provide for notification of the functions concerned?			
	4.13.2Review and Dispositioning of Nonconforming Product			
4	Is the responsibility for review and authority for the disposition of nonconforming product defined?			
5	Is nonconforming product reviewed in accordance with documented procedures?			
	Are the following options considered:			
	a) Rework to meet the specified requirements?			
	b) Accept with or without repair by concession?			
	c) Regrade for alternative standards			
	d) Reject or scrap?			
6	When required by the contract, is the proposed use or repair of the product which does not conform to specified requirements reported for concession to the customer or the customer's representative?			
7	Is the description of the nonconformity that has been accepted, and of repairs, recorded to denote the actual condition?			
8	Is repaired and/or reworked product reinspected in accordance with the quality plan and/or documented procedures?			

4.14 Corrective and Preventive Action

No.	Question	Y	N	Comments
	4.14 Corrective and Preventive Action			
1	Does the supplier have documented procedures for implementing corrective and preventive action?			
2	Is the magnitude of the problem and the risks encountered taken into consideration when corrective and preventive action is taken to eliminate the causes of actual or potential nonconformities?			
3	Are changes to the documented procedures resulting from corrective and preventive action implemented and recorded?			
	4.14.2Corrective Action			
4	Do the procedures for corrective action include: a) The effective handling of customer complaints and reports of product nonconformities?			
	b) Investigation of the cause of nonconformities relating to product, process and quality system, and recording the results of the investigation?			
	c) Determination of the corrective action needed to eliminate the cause of nonconformities?			
	d) Application of controls to ensure that corrective action is taken and that it is effective?			

No.	Question	Y	N	Comments
5	**4.14.3Preventive Action** Do the procedures for preventive action include: a) The use of appropriate sources of information such as: i) Processes and work operations which affect product quality			
	ii) Concessions			
	iii) Audit results			
	iv) Quality records			
	v) Service reports			
	vi) Customer complaints			
	to detect, analyze and eliminate potential causes of nonconfomrities?			
	b) Determination of the steps needed to deal with any problems requiring preventive action?			
	c) Initiation of preventive action and application of controls to ensure that is effective?			
	d) Ensuring that relevant information on actions taken is submitted for management review?			

4.15 Handling, Storage, Packaging, Preservation and Delivery

No.	Question	Y	N	Comments
	4.15.1General			
1	Has the supplier established documented procedures for:			
	a) Handling?			
	b) Storage?			
	c) Packaging?			
	d) Preservation?			
	e) Delivery of product?			
	4.15.2Handling			
2	Does the supplier provide methods of handling product that prevent damage or deterioration?			
	4.15.3Storage			
3	Are designated storage areas or stock rooms used to prevent damage or deterioration of product, pending use or delivery?			
4	Are appropriate methods for authorizing receipt to and dispatch from such areas stipulated?			
5	Is the condition of product in stock assessed at appropriate intervals, in order to detect deterioration?			
	4.15.4Packaging			
6	Are packing, packaging, and marking processes controlled to the extent necessary to ensure conformance to the specified requirements? (Including materials used)			
	4.15.5Preservation			
7	Are appropriate methods for preservation and segregation applied when the product is under the supplier's control?			
	4.15.6Delivery			
8	Has the supplier arranged for the protection of the product after final inspection and test?			
9	Is the protection extended to include delivery to destination where contractually specified?			

4.16 Control of Quality Records

No.	Question	Y	N	Comments
1	Has the supplier established documented procedures for control of quality records and does this procedure include: a) Identification?			
	b) Collection?			
	c) Indexing?			
	d) Access?			
	e) Filing?			
	f) Storage?			
	g) Maintenance?			
	h) Disposition?			
2	Are quality records maintained to demonstrate conformance to specified requirements and the effective operation of the quality system?			
3	Are pertinent quality records from subcontractors an element of these data?			
4	Are all quality records legible?			
5	Are all quality records stored and retained in such a way that they are readily retrievable?			
6	Are all quality records stored in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss?			
7	Are retention times for quality records established and recorded?			
8	Are quality records made available for evaluation by the customer or customer's representative for an agreed period, where agreed contractually?			

4.17 Internal Quality Audits

No.	Question	Y	N	Comments
1	Has the supplier established documented procedures for planning and implementing internal quality audits?			
2	Do these audits verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system?			
3	Are internal quality audits scheduled on the basis and status and importance of the activity to be audited?			
4	Are internal quality audits carried out by personnel independent of those having direct responsibility for the activity being audited?			
5	Are the results of the audit recorded?			
6	Are the results of the audits brought to the attention of the personnel having responsibility in the area being audited?			
7	Do management personnel responsible for the area take timely corrective action on deficiencies found during the audit?			
8	Do follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken?			

4.18 Training

No.	Question	Y	N	Comments
1	Has the supplier established documented procedures for identifying training needs?			
2	Does the supplier provide for the training of all personnel performing activities affecting quality?			
3	Are personnel performing specific assigned tasks qualified on the basis of appropriate education, training and/or experience, as required?			
4	Are appropriate records of training maintained?			

4.19 Servicing

No.	Question	Y	N	Comments
1	Where servicing is a specified requirement, has the supplier established documented procedures for: a) Performing			
	b) Verifying			
	d) Reporting			
	that servicing meets the specified requirements?			

4.20 Statistical Techniques

No.	Question	Y	N	Comments
1	**4.20.1Identification of Need** Has the supplier identified the need for statistical techniques required for: a) Establishing b) Controlling c) Verifying process capability and product characteristics?			
2	**4.20.2Procedures** Has the suppler established documented procedures to implement and control the application of the statistical techniques identified above?			

DNV Certification, Inc.

Assessment Checklist

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